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OCT 06 2006

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| From: David S. Resnick Candace M. Summerford | Date: 10/6/06 | No. of Pages: (including this page) 30 | 701826-050025-C |
|---|---------------|---|-----------------|

Comments:

In re application of: Bruce R. ZETTER, Lloyd HUTCHINSON and Lere BAO
 Confirmation No.: 6593
 Application No.: 10/537,455 Group No.: 1634
 Filed: 10/31/2005 Examiner: To be assigned
 For: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

1. Certificate of Facsimile (1 pg.);
2. Transmittal Form (1 pg);
3. Request for Corrected Filing Receipt – PTO Error (2 pp.);
4. COPY - Filing Receipt with Corrections Marked in Ink (3 pp.);
5. COPY – Previously Submitted Request for Corrected Filing Receipt (1 pg.);
6. COPY - Previously Submitted Filing Receipt with Corrections Marked in Ink (3 pp.);
7. COPY – Coversheet to Corresponding Published International Application (1 pg.);
8. COPY – Previously Submitted Preliminary Amendment (6 pp.);
9. COPY – Previously Submitted Declaration and Power of Attorney Form (4 pp.); and
10. COPY – Previously Submitted Supplemental Application Data Sheet (7 pp.).

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Practitioner's Docket No. 701039-050025

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bruce R. ZETTER, Lloyd HUTCHINSON and Lere BAO
Confirmation No.: 6593
Application No.: 10/537,455 Group No.: 1634
Filed: 10/31/2005 Examiner: To be assigned
For: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

CERTIFICATION OF FACSIMILE TRANSMISSION

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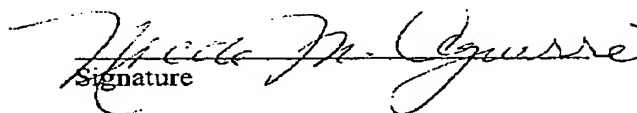
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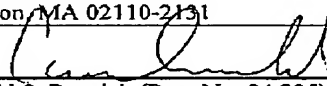

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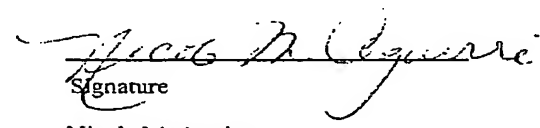
Nicole M. Aguirre
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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | | Application Number | 10/537,455 | OCT 06 2006 |
|---|--|------------------------|-----------------|--------------------|
| | | Filing Date | 10/31/2005 | |
| | | First Named Inventor | Bruce R. Zetter | |
| | | Group Art Unit | 1634 | |
| | | Examiner Name | To be assigned | |
| Total Number of Pages in This Submission | | Attorney Docket Number | 701039-050025 | |

| ENCLOSURES (check all that apply) | | |
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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Declaration and Power of Attorney <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Application Data Sheet <input checked="" type="checkbox"/> Request for Corrected Filing Receipt with Enclosures <input type="checkbox"/> A self-addressed prepaid postcard for acknowledging receipt <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Certificate of Facsimile |
| Remarks | | <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees required or credit any overpayments to Deposit Account No. 19-2380 for the above identified docket number. |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | |
|---|---|
| Firm or Individual name | NIXON PEABODY LLP 100 Summer Street Boston, MA 02110-2131 |
| Signature |  David S. Resnick (Reg. No. 34,235) / Candace M. Summerford (Reg. No. 58,109) |
| Date | 10/6/06 |

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Practitioner's Docket No. 701039-050025

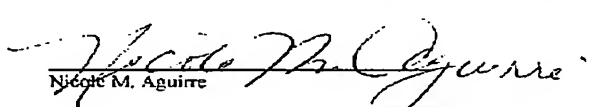
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Confirmation No.: 6593
Application No.: 10/537,455 Group No.: 1634
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For: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

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| CERTIFICATE OF FACSIMILE | |
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REQUEST FOR CORRECTED FILING RECEIPT – PTO ERROR

1. Attached is a copy of the 09/08/2006 official corrected filing receipt received from the PTO in the above application for which issuance of a corrected filing receipt is respectfully requested.
2. There are errors with respect to the following, which are incorrectly entered.

*Error in**Correct data*

- | | |
|---|----------------|
| i) Domestic Priority data - International Filing Date | i.) 01/09/2004 |
|---|----------------|

Applicants attach hereto a copy of the filing receipt with corrections marked in red ink.

3. Applicants note that the correct information for the priority data has been submitted to the U.S. PTO in the Coversheet to the corresponding Published International Application; in the Preliminary Amendment filed on July 1, 2005, as well as in the Executed Declaration/Power of Attorney and Supplemental Application Data Sheet filed on October 26, 2005. In addition, Applicants requested the information be corrected in the Request for Corrected Filing Sheet previously filed on March 23, 2006; however, the correction was overlooked. Copies of these previously filed documents are attached hereto.

Request for Corrected Filing Receipt—page 1 of 2

In re application of: Bruce R. ZETTER, Lloyd HUTCHINSON and Lere BAO
Confirmation No.: 6593
Application No.: 10/537,455 Group No.: 1634
Filed: 10/31/2005 Examiner: To be assigned
For: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

4. Applicants do not believe any fees are associated with this submission. Authorization to charge fee deficiencies and credit overpayment to the NIXON PEABODY LLP Deposit Account No. 19-2380 is given in the event that Applicants are mistaken.
5. The Examiner is asked to kindly contact the undersigned with any questions regarding this matter.

Date: 10/6/06



David S. Resnick (Reg. No.: 34,235)
Candace M. Summerford (Reg. No. 58,109)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110-2131
Tel. No.: 617-345-6057 / 1104

Request for Corrected Filing Receipt--page 2 of 2

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Page 1 of 3

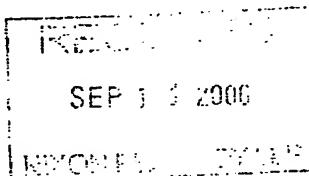
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| APPL NO. | FILING OR 371 (c) DATE | ART UNIT | FIL FEE REC'D | ATTY. DOCKET NO | DRAWINGS | TOT CLMS | IND CLMS |
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| 10/537,455 | 10/31/2005 | 1634 | 565 | 701039-050025 | 6 | 24 | 4 |

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BOSTON, MA 02110-2131

CONFIRMATION NO. 6593

CORRECTED FILING RECEIPT



OC000000020359151

Date Mailed: 09/08/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Bruce R Zetter, Wayland, MA;
Lloyd Hutchinson, Arlington, MA;
Lere Bao, Maynard, MA;

Assignment For Published Patent Application

Children's Medical Center Corporation, Boston, MA

Power of Attorney: The patent practitioners associated with Customer Number 50828.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/00447 ~~01/07/2004~~ 01/09/2004
which claims benefit of 60/438,861 01/09/2003
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications

If Required, Foreign Filing License Granted: 02/09/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/537,455**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Methods for diagnosis and prognosis of cancer

Preliminary Class

435

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Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Practitioner's Docket No. 701039-050025

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bruce R. ZETTER, Lloyd HUTCHINSON and Lere BAO
Confirmation No.: 6593
Application No.: 10/537,455 Group No.: 1634
Filed: 10/31/2005 Examiner: To be assigned
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REQUEST FOR CORRECTED FILING RECEIPT - PTO ERROR

1. Attached is a copy of the official filing receipt received from the PTO in the above application for which issuance of a corrected filing receipt is respectfully requested.
2. There are errors with respect to the following, which are incorrectly entered.

*Error in**Correct data*

i) Applicant's address for Lere Bao
"Maryland" is incorrect

i.) Maynard

ii) Domestic Priority data - International Filing Date ii.) 01/09/2004

Applicants' attach hereto a copy of the filing receipt with corrections marked in red ink.

3. Applicants note that the correct information for the priority data has been submitted to the U.S. PTO in the Coversheet to the corresponding Published International Application; in the Preliminary Amendment filed on July 1, 2005, as well as in the Executed Declaration/Power of Attorney and Supplemental Application Data Sheet filed on October 26, 2005. In addition, the correct address for Lere Bao has also been listed in the executed Declaration/Power of Attorney form and the Supplemental Application Data Sheet. Copies of these previously filed documents are attached hereto.
4. Applicants do not believe any fees are associated with this submission. Authorization to charge fee deficiencies and credit overpayment to the NIXON PEABODY LLP Deposit Account No. 50-0850 is given in the event that Applicants are mistaken.

Date: 3/23/06

David S. Resnick (Reg. No.: 34,235)
Candace M. Summerford (Reg. No. 58,109)
NIXON PEABODY LLP
100 Summer Street
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Tel. No.: 617-345-6057

Request for Corrected Filing Receipt--page 1 of 2

OCT 06 2006

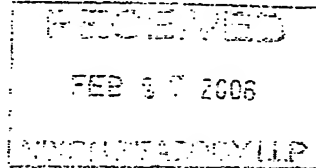


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| APPL NO. | FILING OR 371 (c) DATE | ART UNIT | FIL FEE RECD | ATTY. DOCKET NO | DRAWINGS | TOT CLMS | IND CLMS |
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| 10/537,455 | 10/31/2005 | 1634 | 565 | 701039-050025 | 6 | 24 | 4 |

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CONFIRMATION NO. 6593

FILING RECEIPT

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Date Mailed: 02/22/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

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Maynard

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Power of Attorney: The patent practitioners associated with Customer Number 50828.

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This application is a 371 of PCT/US04/00447 01/07/2004 * 01/09/2004
which claims benefit of 60/438,861 01/09/2003
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications

If Required, Foreign Filing License Granted: 02/09/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/537,455**

Projected Publication Date: 05/18/2006

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ******RECEIVED
CENTRAL FAX CENTER****OCT 06 2006****Title**

Methods for diagnosis and prognosis of cancer

Preliminary Class

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PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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LICENSE FOR FOREIGN FILING UNDER**Title 35, United States Code, Section 184****Title 37, Code of Federal Regulations, 5.11 & 5.15****GRANTED**

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license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 July 2004 (29.07.2004)

PCT

(10) International Publication Number
WO 2004/063712 A3

(51) International Patent Classification⁷: C12Q 1/68, C12P
19/34, C07H 21/02, 21/04, G01N 33/574, C07K 14/435

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PCT/US2004/000447

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kind of national protection available): AE, AG, AL, AM,

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kind of regional protection available): ARIPO (BW, GH,
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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

(57) Abstract: We have discovered a protein in humans, herein referred to as thymosin R16 (SEQ ID NO: 1), that is expressed in human prostate cancer tumors but not in specimens of benign prostate hyperplasia (BPH) tissues. In contrast, prostate specific antigen (PSA), the gold standard of prostate cancer diagnosis, is highly expressed in BPH tissues. Increased expression of thymosin (316 has a high correlation to disease state in a number of cancers including prostate cancer and cancers of epithelial origin. Accordingly, method of diagnosing and prognosing cancer in a patient by measuring the level of thymosin (316 in a biological test sample obtained from the patient are provided.

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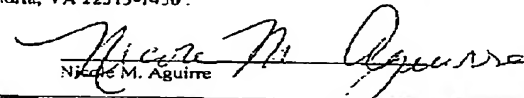
Practitioner's Docket No. 701039-050025-US

PATENT

IN THE UNITED STATES RECEIVING OFFICE

| International Application Number | International Filing Date | International Earliest Priority Date |
|----------------------------------|-------------------------------|--------------------------------------|
| PCT/US2004/000447 | 09 January 2004 09.01.2004 | 09 January 2003 09.01.2003 |

TITLE OF INVENTION: METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER
APPLICANTS FOR DO/US: CHILDREN'S MEDICAL CENTER CORPORATION
INVENTORS FOR DO/US: ZETTER, Bruce; HUTCHINSON, Lloyd; BAO, Lere
U.S. SERIAL NO.: TO BE ASSIGNED

| CERTIFICATE OF MAILING | |
|--|---|
| I hereby certify that this correspondence, on the date shown below, is being deposited with the United States Postal Service with sufficient postage as Express Mail Label No. <u>EV 653000627 US</u> in an envelope addressed to MAIL STOP PCT, Commissioner of Patents, Box 1450, Alexandria, VA 22313-1450. | |
| Date: <u>7/1/05</u> |  Nicole M. Aguirre |

MAIL STOP PCT
Commissioner for Patents
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PRELIMINARY AMENDMENT

This Preliminary Amendment is being filed in the U.S. Patent and Trademark Office concurrently with the 371 National Entry of the above-identified application.

Preliminary to calculation of the filing fee and examination on the merits, please amend the application identified in caption as follows:

Amendments to the Specification are reflected on page 2 of this paper.

Amendments to the claims begin on page 3 of this paper.

Remarks/Arguments begin on page 6 of this paper.

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NIXON PEABODY

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U.S. Serial No.: [REDACTED] assigned
(371 Nat'l Entry of PCT/US2004/000447)
Preliminary Amendment Filed 07/01/2005

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IN THE SPECIFICATION

Please add the following heading/first paragraph on page 1, line 1 of the application:

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 371 National Stage of International Application No. PCT/US2004/000447 filed on January 9, 2004, which designated the U.S., and which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/438,861 filed on January 9, 2003.

U.S. Serial No.: To be assigned
(371 Nat'l Entry of PCT/US2004/000447)
Preliminary Amendment Filed 07/01/2005

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IN THE CLAIMS

Please amend the claims as follows:

CLAIMS

We claim:

1. (ORIGINAL) A method of diagnosing cancer in a patient, comprising:
 - a) obtaining a test sample from a patient;
 - b) measuring the level of thymosin β 16 in the test sample; and
 - c) comparing the level of thymosin β 16 in the test sample with the level of thymosin β 16 present in a normal control sample;wherein a higher level of thymosin β 16 in the test sample as compared to the level in the normal control sample is indicative of cancer.
2. (ORIGINAL) The method of claim 1, wherein said test sample and said normal control sample are selected from the group consisting of blood, tissue, serum, stool, urine, sputum, cerebrospinal fluid, nipple aspirates, and supernatant from cell lysate.
3. (ORIGINAL) The method of claim 1, wherein the cancer is prostate cancer, lung carcinoma, breast carcinoma, thyroid carcinoma, brain cancers (cerebellum, medulloblastoma, astrocytoma, ependymoma, glioblastoma), pancreatic carcinoma, ovarian carcinoma, eye cancer (retinoblastoma), muscle (rhabdomyosarcoma), lymphoma, stomach cancer, liver cancer, colon cancer, kidney cancer.
4. (ORIGINAL) A method for prognostic evaluation of a patient suspected of having or having cancer comprising:
 - a) measuring the level of thymosin β 16 in a test sample obtained from a patient;
 - b) comparing the level determined in step (a) to a range of thymosin β 16 known to be present in a biological sample obtained from a normal patient that does not have cancer; and
 - c) evaluating the prognosis of said patient based on the comparison of step (b), wherein a high level of thymosin β 16 in step (a) indicates an aggressive form of cancer and therefore a poor prognosis.

U.S. Serial No. [REDACTED] be assigned
(371 Nat'l Entry of PCT/US2004/000447)
Preliminary Amendment Filed 07/01/2005

5. (ORIGINAL) The method of claim 4, wherein said test sample is selected from the group consisting of blood, tissue, serum, stool, urine, sputum, cerebrospinal fluid, nipple aspirates, and supernatant from cell lysate.
6. (ORIGINAL) The method of claim 4, wherein the cancer is prostate cancer, lung carcinoma, breast carcinoma, thyroid carcinoma, brain cancers (cerebellum, medulloblastoma, astrocytoma, ependymoma, glioblastoma), pancreatic carcinoma, ovarian carcinoma, eye cancer (retinoblastoma), muscle (rhabdosarcoma), lymphoma, stomach cancer, liver cancer, colon cancer, kidney cancer.
7. (CURRENTLY AMENDED) The method of claim 1 ~~or 4~~, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 mRNA.
8. (ORIGINAL) The method of claim 7, wherein the mRNA is detected by use of an RNA dependent polymerase chain reaction.
9. (ORIGINAL) The method of claim 7, wherein the mRNA is detected by Northern blot analysis by hybridizing mRNA from said test sample or said control sample to a thymosin β 16 nucleotide probe.
10. (ORIGINAL) The method of claim 7, wherein the mRNA is detected by DNA microarray analysis.
11. (CURRENTLY AMENDED) The method of claim 1 ~~or 4~~, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 protein.
12. (ORIGINAL) The method of claim 11, wherein thymosin β 16 protein level is measured by Mass Spectrometry.
13. (ORIGINAL) The method of claim 11, wherein the method of measuring the level of thymosin β 16 levels comprises the steps of:
 - a) contacting a sample or preparation thereof with an antibody or antibody fragment which selectively binds thymosin β 16; and
 - b) detecting whether said antibody or said antibody fragment is bound by said sample and thereby measuring the levels of thymosin β 16 present.
14. (ORIGINAL) The method according to claim 13 wherein said antibody, or said antibody fragment, is detectably labeled.

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(371 Nat'l Entry of PCT/US2004/000447)
Preliminary Amendment Filed 07/01/2005

15. (ORIGINAL) A kit for measuring thymosin β 16 levels comprising separate vials containing antibodies, or antibody fragments, which selectively bind human thymosin β 16.
16. (ORIGINAL) A kit for measuring thymosin β 16 levels comprising at least one polynucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO:2 or SEQ ID NO:3.
17. (NEW) The method of claim 4, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 mRNA.
18. (NEW) The method of claim 17, wherein the mRNA is detected by use of an RNA dependent polymerase chain reaction.
19. (NEW) The method of claim 17, wherein the mRNA is detected by Northern blot analysis by hybridizing mRNA from said test sample or said control sample to a thymosin β 16 nucleotide probe.
20. (NEW) The method of claim 17, wherein the mRNA is detected by DNA microarray analysis.
21. (NEW) The method of claim 4, wherein the level of thymosin β 16 is measured by measuring the levels of thymosin β 16 protein.
22. (NEW) The method of claim 21, wherein thymosin β 16 protein level is measured by Mass Spectrometry.
23. (NEW) The method of claim 21, wherein the method of measuring the level of thymosin β 16 levels comprises the steps of:
 - a) contacting a sample or preparation thereof with an antibody or antibody fragment which selectively binds thymosin β 16; and
 - b) detecting whether said antibody or said antibody fragment is bound by said sample and thereby measuring the levels of thymosin β 16 present.
24. (NEW) The method according to claim 23 wherein said antibody, or said antibody fragment, is detectably labeled.

U.S. Serial No.: [REDACTED] assigned
(371 Nat'l Entry of PCT/US2004/000447)
Preliminary Amendment Filed 07/01/2005

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REMARKS

By the present Preliminary Amendment, Applicants have amended the specification to add the cross-reference heading/paragraph. No new matter has been added by virtue of this amendment and its entry is respectfully requested.

Applicants have amended claims 7 and 11 and added claims 17 - 24. Support for these amendments can be found throughout the application and in claims 7 - 14 as originally filed. No new matter has been added by virtue of these amendments and their entry is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it is kindly requested that the Examiner contact the undersigned attorney concerning the same to expedite prosecution of this application.

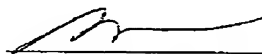
Entry of the foregoing and prompt and favorable consideration of the subject application on the merits are respectfully requested.

Fee deficiencies associated with the submission of this document may be charged to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Customer No. 50828

Date: 7/1/05

Respectfully submitted,


David S. Resnick (Reg. No. 34,235)
NIXON PEABODY LLP
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(617) 345-6057

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NIXON PEABODY LLP
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Boston, Massachusetts 02110-2131

Attorney's Docket No. 701039-050025-US

Page 1 of 4

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that: My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed at 201) below or an original, first and joint inventor (if plural names are listed at 201-208 below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

which is described and claimed in:

- ☐ the specification attached hereto.
- ☐ the specification in U.S. Application Serial Number _____ filed on _____.
- ☒ the specification in PCT International Application Number PCT/US2004/000447 filed on 09 January 2004.
- ☒ I have reviewed the preliminary amendment filed concurrently with the specification which is part of the application as filed;

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

| Prior Foreign/PCT Applications and Any Priority Claims Under 35 U.S.C. §119: | | | |
|--|-------------|---------|--|
| Application No. | Filing Date | Country | Priority Claimed under 35 U.S.C. §119? |
| | | | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | | | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | | | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | | | <input type="checkbox"/> YES <input type="checkbox"/> NO |

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose material information as defined in 37 CFR §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

BO3653175.1

- 2 -

| Prior U.S. Applications or PCT International Applications Designating the U.S. Benefit | | | | | |
|--|------------------|--------------------------|---------|-----------|--|
| under 35 U.S.C. §120 | | | | | |
| U.S. Applications | | Status (Check One) | | | |
| Application Serial No. | U.S. Filing Date | Patented | Pending | Abandoned | |
| | | | | | |
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| PCT Applications Designating the U.S. | | | | | |
| Application No. | Filing Date | U.S. Serial No. Assigned | | | |
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CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. §119(e))

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

| Applicant | Provisional Application Number | Filing Date |
|---------------|--------------------------------|-------------|
| Zetter et al. | 60/438,861 | 01/09/2003 |
| | | |
| | | |

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) with full powers of association, substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| | | | | | |
|----------------------|-------------------|------------------|-------------------|--------------------|-------------------|
| Ronald I. Eisenstein | (Reg. No. 33,628) | David S. Resnick | (Reg. No. 34,235) | Michael L. Goldman | (Reg. No. 30,727) |
| Nicole L.M. Valiz | (Reg. No. 47,150) | Leena Kantunen | (LD207) | Georgia Evans | (Reg. No. 44,957) |
| Gunnar G. Leinberg | (Reg. No. 33,584) | Edwin V. Merkel | (Reg. No. 40,087) | Joseph Noto | (Reg. No. 32,163) |

| | |
|--|---|
| SEND CORRESPONDENCE TO: David S. Resnick NIXON PEABODY LLP 100 Summer Street Boston, Massachusetts 02110-2131 | DIRECT TELEPHONE CALLS TO: David S. Resnick (617) 345-6057 |
|--|---|

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- 3 -

| | | | | |
|-------------|-------------------------|--|--------------------------------|---|
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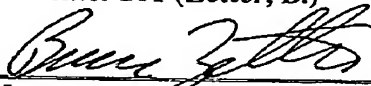


| | | | | |
|-------------|-------------------------|--|---|---|
| 2 0 2 | FULL NAME OF INVENTOR | LAST NAME HUTCHINSON | FIRST NAME LLOYD | MIDDLE NAME |
| | RESIDENCE & CITIZENSHIP | CITY ARLINGTON <i>MA</i> Brookline <i>7/13/05</i> | STATE OR FOREIGN COUNTRY MA | COUNTRY OF CITIZENSHIP US <i>CANADA</i> <i>7/13/05</i> |
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BOS655178.1

- 4 -

I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| | |
|---|------------------|
| Signature of Inventor 201 (Zetter, B.)  | Date: 7/8/05 |
| Signature of Inventor 202 (Hutchinson, L.)  | Date: 7/18/05 |
| Signature of Inventor 203 (Bao, L.)  | Date: 8/1/05 |

BDS655178.1

SUPPLEMENTAL APPLICATION DATA SHEET

APPLICATION INFORMATION

| | |
|----------------------------------|---|
| Application number:: | 10/537,455 |
| Filing Date:: | |
| Application Type:: | 371 National Entry |
| Subject Matter:: | Utility |
| Suggested classification:: | |
| Suggested Group Art Unit:: | |
| CD-ROM or CD-R?:: | None |
| Number of CD disks:: | |
| Number of copies of CDs:: | |
| Sequence submission?:: | No |
| Computer Readable Form (CRF)?:: | |
| Number of copies of CRF:: | |
| Title:: | METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER |
| Attorney Docket Number:: | 701039-050025 |
| Request for Early Publication?:: | No |
| Request for Non-Publication?:: | No |
| Suggested Drawing Figure:: | 1 |
| Total Drawing Sheets:: | 6 |
| Small Entity?:: | Yes |
| Latin name:: | |
| Variety denomination name:: | |
| Petition included?:: | No |
| Petition Type:: | |

371 Nat'l Entry of PCT/US2004/000255
SUPPLEMENTAL Application Data Sheet - 09/06/2005
Page 1 of 7

| | |
|---------------------------------|-------------------------------------|
| Licensed US Govt. Agency:: | National Institutes of Health (NIH) |
| Contract or Grant Numbers:: | R01CA37393 |
| Secrecy Order in Parent App.?:: | |

APPLICANT INFORMATION

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| Applicant Authority Type:: | Inventor |
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OR

| Representative Designation:: | Registration Number:: | Representative Name:: |
|------------------------------|-----------------------|-----------------------|
| Attorney of Record | 30,628 | Ronald I. Eisenstein |
| Attorney of Record | 34,235 | David S. Resnick |
| Agent | 47,150 | Nicole L.M. Valtz |
| Agent | L0207 | Leena H. Karttunen |
| Attorney | 30,727 | Michael L. Goldman |

DOMESTIC PRIORITY INFORMATION

| Application:: | Continuity Type:: | Parent Application:: | Parent Filing Date:: |
|-------------------|---|----------------------|----------------------|
| This application | National Stage of | PCT/US2004/000447 | 01/09/2004 |
| PCT/US2004/000447 | An application claiming the benefit under 35 USC 119(e) | 60/438,861 | 01/09/2003 |

371 Nat'l Entry of PCT/US2004/000255
SUPPLEMENTAL Application Data Sheet - 09/08/2005
Page 6 of 7

FOREIGN PRIORITY INFORMATION

| Country:: | Application number:: | Filing Date:: | Priority Claimed:: |
|-----------|-------------------------|------------------|-----------------------|
| | | | |

ASSIGNEE INFORMATION

| | |
|--|--|
| Assignee name:: | Children's Medical Center Corporation |
| Street of mailing address:: | 55 Shattuck Street |
| City of mailing address:: | Boston |
| State or Province of mailing address:: | MA |
| Country of mailing address:: | US |
| Postal or Zip Code of mailing address:: | 02115 |

Date: _____ Respectfully submitted,

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